How Much Kyphosis is Allowable for Cervical Total Disc Replacement?

And Other Considerations

Richard D. Guyer, M.D.

Texas Back Institute

Disclosures

Guyer	(a) Alphatec; (b) Spinal Kinetics, Spinal Ventures, Mimedix; (c) DePuy-Synthes Spine, K2M, Flexuspine, Mimedix, Aescalup; Safe Orthopedics (d) DePuy-Synthes Spine, K2M, Paradigm Spine

Key: (a) royalties; (b) stock/options; (c) consulting/SAB; (d) Speaker/ faculty; (e) Research; (f) Fellowship and related research; (g) other

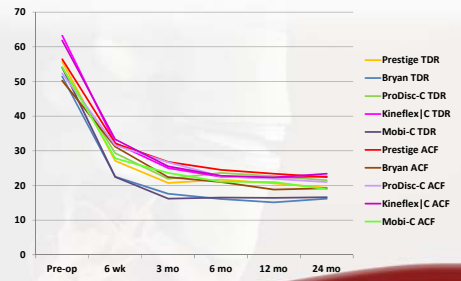
Texas Back Institute

Introduction

- Cervical TDR gaining acceptance as an alternative to fusion for treatment of common cervical pathologies
- Prospective, randomized FDA IDE studies consistently find results of TDR to be similar or superior to ACDF
  - Maintained through ≥5 yr follow-up

Texas Back Institute

Mean NDI Scores for TDR and ACF in Various FDA IDE Trials showing similar results



Texas Back Institute

Basic Indications

- Cervical degenerative disc disease 1 or 2 levels for cervical radiculopathy and/or myelopathy, +/- neck pain
- Failed ≥6 wks non-op care or progressive neuro symptoms
- Imaging studies correlating with symptoms

Texas Back Institute

Basic Contra-indications

- Ankylosing spondylitis, rheumatoid arthritis, ossification of PLL
- Prior cervical spinal infection
- Chronic steroid use or a medical condition requiring chronic steroids
- Morbid obesity
- Pregnancy
- Axial neck pain as the solitary symptom

Texas Back Institute

What About Pre-op Kyphosis and CTDR?

- Severe, fixed – exclude
- No literature available to define values for extent of kyphosis acceptable for cervical TDR

Texas Back Institute

What About Kyphosis and CTDR?

- Should consider:
  - Is there significant facet joint degeneration
  - Can good alignment be achieved
  - Can TDR be adequately positioned to allow motion
  - How reversible is it??

Texas Back Institute

Alignment Matters

Historically cervical alignment was segmental

- C1-C2 lordosis
- C2-C7 lordosis
- Segmental Lordosis

Texas Back Institute

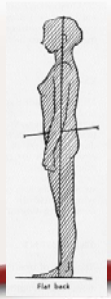
Alignment Matters – Global is Important

PI = Fixed (SS+PT)

LL = SS + PT (+ 10°)

LL↓ = SS ↓, PT ↑

Flat Back



Texas Back Institute

An Original Study

Am J Orthop. 2012;41(6):E81-E84.

Correlation Between Cervical Spine Sagittal Alignment and Clinical Outcome After Anterior Cervical Discectomy and Fusion

Jeffrey L. Gum, MD, Steven D. Glassman, MD, Lonnie R. Douglas, MD, and Leah Y. Carreon, MD, MSc

Texas Back Institute

An Original Study

Am J Orthop. 2012;41(6):E81-E84.

Correlation Between Cervical Spine Sagittal Alignment and Clinical Outcome After

One hundred one patients (75 female; mean age, 52 years) were included. There was improvement in all HRQOL measures from preoperative to 2 years postoperative. There was no significant difference in preoperative and 2-year postoperative sagittal alignment. Receiver operating characteristic curve analysis showed that a postoperative cervical lordosis of at least 6° predicted achievement of MCID for NDI (8 point change in NDI).

This suggests that maintenance or restoration of overall cervical lordosis is important in achieving a successful result after ACDF.

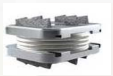
None of the current approved semi-constrained CTDRs are able to correct deformity except when secondary to radiculopathy

- Bryan (2009)
- Prestige (2007)
- Prestige LP (2014) 1 and 2 level
- ProDisc-C (2007)
- SeCure-C (2012)
- PCM (2012)
- Mobi-C (1 and 2-level)

Texas Back Institute

Nor Can Any of these Discs

- Trial completed
  - Kineflex|C
- Trials ongoing
  - M6
  - Simplify (1 and 2 level studies)
- Trials ended
  - Discover
  - Neodisc
  - Cervicore



Texas Back Institute

Feature Article

Orthopaedics 36(7):e958-65, 2013

Cervical Disk Arthroplasty Versus ACDF for Preoperative Reducible Kyphosis

YU CHEN, MD; XINWEI WANG, MD; XUHUA LU, MD; HAISONG YANG, MD; DEYU CHEN, MD

- Defined pre-op kyphosis:
  - Reducible: mostly related to disc prolapse, clinical symptoms, and muscle weakness
  - Irreducible: associated with significant cervical degeneration or congenital bone malformation
- Randomized 32 pts to Discover TDR vs. ACDF with cage+plate
- 24 mo follow-up

Texas Back Institute

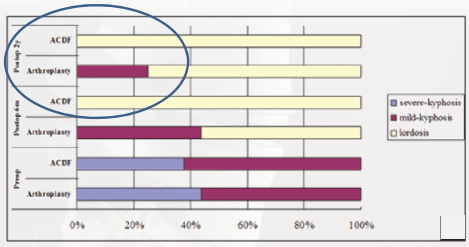
Pre-op Reducible Kyphosis

- No significant differences in clinical or radiographic results at 2-yr follow-up
- Global and functional spinal unit angles of TDR arthroplasty group significantly lower than in ACDF group 6 mo post-op, consistent with NDI scores
- Sagittal alignment of cervical spine, index level, and NDI improved significantly after 6 mo in TDR group but not ACDF
- Reducible kyphosis is not a contraindication for TDR
- Neck strengthening exercises should be emphasized for post-op rehab following TDR

Chen et al, Orthopaedics, 2013

Texas Back Institute

TDR vs. ACDF in Reducible Kyphosis



Chen et al, Orthopaedics, 2013

Texas Back Institute

Pre- and Post-TDR in a Patient with Cervical Kyphosis

Chen et al, Orthopaedics, 2013

Journal of Spinal Disorders & Techniques

J Spinal Disord Tech. 2012 Feb;25(1):10-6. doi: 10.1097/BSD.0b013e31820f91

Sagittal alignment after single cervical disc arthrop

Guérin P[1], Obeid I, Gille O, Bourghli A, Luc S, Pointillart V, Vital JM.

In our study, we found no correlation between sagittal balance parameters and ROM. The unconstrained nature of the device with the presence of a mobile insert and 5 degrees of freedom probably contributed to these results. Moreover, the only observed clinical correlations were between postoperative FSU angle and postoperative PCS SF-S36, between change of FSU angle and PCS SF-36, and between prosthesis shell angle and postoperative VAS neck pain. No correlation was found between overall cervical spine curvature and clinical outcomes. The improvement in clinical outcomes was probably attributable to neuro-

Texas Back Institute

Analysis of Factors That May Predict Segmental ROM after Cervical TDR: A 7-years Retrospective Study

- **Conclusions:**
  - **Patients with pre-op kyphosis or lordosis did not demonstrate any differences with respect to post-op clinical outcomes or segmental ROM**
    - **Therefore these should not be considered independent contra-indications for TDR**
  - **Investigation is necessary in order to determine how to choose kyphotic patients**

Tian et al, Clin Spine Surg, in press

Texas Back Institute

What Are Other Important Selection Criteria for Cervical TDR that may affect alignment?

- **Some patients may be TDR candidates based on published criteria**
  - **Other practical factors to consider, including patient vs. implant size**

Texas Back Institute

Eur Spine J 2013
DOI 10.1007/s00586-012-2594-3

ORIGINAL ARTICLE

Footprint mismatch in total cervical disc arthroplasty

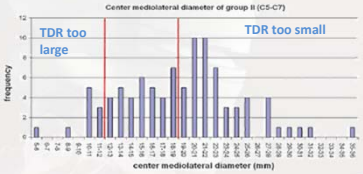
Martin Thaler · Sebastian Hartmann · Michaela Gstöttner · Ricarda Lechner · Michael Gabl · Christian Bach

- Conclusion: pt vs. implant size mismatch may endanger safety and efficacy
- Undersized TDR may lead to subsidence, loosening, HO, and/or biomechanical failure caused by an incorrect center of rotation and load distribution, affecting facet joints

Texas Back Institute

Patient vs. TDR Size

- ProDisc-C footprint sizes fall within red lines, grey bars represent number of patients measured



Thaler et al, Europ Spine J, 2013

Texas Back Institute

Chinese Medical Journal ¦ January 20, 2015 ¦ Volume 128 ¦ Issue 2

Original Article

Footprint Mismatch of Cervical Disc Prostheses with Chinese Cervical Anatomic Dimensions

Liang Dong[1,2], Ming-Sheng Tan[1,2], Qin-Hua Yan[1], Ping Yi[1], Feng Yang[1], Xiang-Sheng Tang[1], Qing-Ying Hao[1]
[1]Department of Orthopedics Surgery, China-Japan Friendship Hospital, Beijing 100029, China
[2]Graduate School of Peking Union Medical College, Beijing 100730, China
[3]Beijing University of Chinese Medicine, Beijing 100029, China

- In addition to footprint mismatch, found that among smallest TDRs available, 36% were too high for the disc space
- May influence ROM and/or cause post-op discomfort through stressing joint capsules and ligaments of Luschka and facet joints

Texas Back Institute

Bone Quality

- Device subsidence attributed to poor bone quality
- May result in kyphosis

Kibuule, Seminars Spine Surg, 2009

Texas Back Institute

Implant Considerations

- Multi-level TDR
- Keeled devices
  - May merit extra attention to:
    - Vertebral body endplate curvature
    - Size of keels vs. vertebral body ht particularly for 2-level cases
    - Rarely reported vertebral split fractures
    - Secondary loss of alignement

Texas Back Institute

Indications for Hybrid Surgery?

- Not included in prospective RCTs / FDA trials
- In general, if patient is indicated at one level for TDR and not the other, hybrid appears to be good option

Texas Back Institute

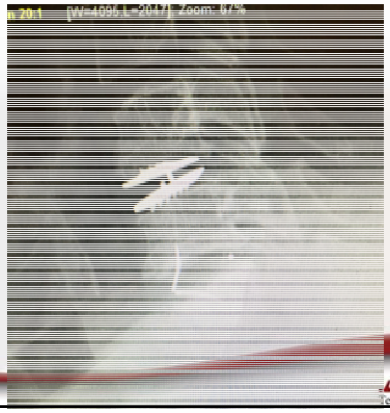
SPINE Volume 34, Number 11, pp 1153–1159
©2009, Lippincott Williams & Wilkins

Artificial Disc Replacement Combined With Fusion *Versus* Two-Level Fusion in Cervical Two-Level Disc Disease

Dong Ah Shin, MD,* Seong Yi, MD,† Do Heum Yoon, MD, PhD,† Keung Nyun Kim, MD, PhD,† and Hyun Cheol Shin, MD, PhD‡

- **Hybrid is superior to 2-level ACF based on better NDI recovery, less post-op neck pain, faster C2-C7 ROM recovery, and less adjacent ROM increase**
- **May correct kyphosis with lordotic fusion cage (RDG)**

Texas Back Institute



Texas Back Institute

Discussion

- **Strong literature to support safety and effectiveness of cervical TDR in appropriately selected patients**
- **Selection criteria well defined and consistent across multiple RCTs**
- **Can refine indications based on biomechanical studies, reported complications, and experience**

Texas Back Institute

Discussion

- However no clear parameters for degree of kyphosis.
- In general if not fixed and reversible, probably a TDR candidate
- If fixed, current TDRs mechanically are not robust enough to correct or constrained enough to restore sagittal alignment
- For multi-level disease consider hybrid construct correcting kyphosis with lordotic fusion cage and TDR above

Texas Back Institute

Thank You

Finally do not improvise and leave the Casper pin in the wound before having your PA close NOT FAKE NEWS!!!!

Texas Back Institute

J Spinal Disord Tech • Volume 21, Number 6, August 2008

ORIGINAL ARTICLE

Correlation of ProDisc-C Failure Strength With Cervical Bone Mineral Content and Endplate Strength

Xingkai Zhang, MD, Nathaniel R. Ordway, MS,† Rong Tan, MD,‡ Byeong Cheol Rim, MD,§ and Amir H. Fayyazi, MD†*

- **Biomechanical cadaveric study**
- **Found correlation between BMD and TDR/endplate failure stress**

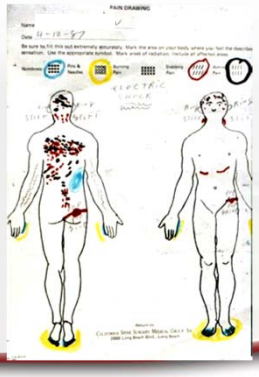
Texas Back Institute

Texas Back Institute

Selection Criteria

- **Indications can be refined by reviewing literature and reported complications**

Texas Back Institute



Avoid pts with psych problems
Not a good candidate for TDR … or other surgery

Texas Back Institute

Patient vs. TDR Size

- Patient really wanted PCM TDR
- Smallest size used, still too large for space
  - Migrated anteriorly soon after implantation
- Removed and replaced with ProDisc-C

Texas Back Institute

Extrusion

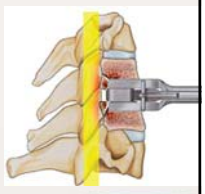
- Authors cautioned that patients with excessive ligamentous laxity should be treated with caution as compromised tissues may contribute to displacement

Kibuule, Seminars Spine Surg, 2009

Texas Back Institute

Vertebral Body Avulsion Fracture

- Noted intra-op
- Bone fragments pushed into canal were remove
- TDR implanted as planned
  - Attributed to keel design and during chiseling inserting instruments past the posterior ends of the keel cuts



Shim J Spinal Disord Tech, 2007

Texas Back Institute

MRI

Herniated disc C5-6

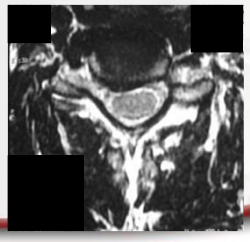


Plate Removal and TDR

Extension

Flexion

Texas Back Institute

Spine
SPINE Volume 41, Number 5, pp 419–428

LITERATURE REVIEW

Comparing Nonrandomized Observational Studies With Randomized Controlled Trials in Cervical Disc Arthroplasty

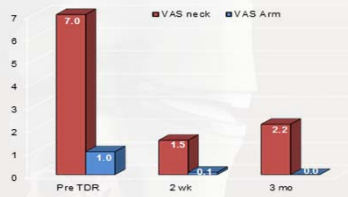
A Meta-analysis

Young Min Jee, BS, MBiotech, John Seongweon Bak, BS, MA, Eric Weinlander, BA, and Paul A. Anderson, MD

- **Results of RCTs were reproduced in observational studies, provided same selection criteria employed**

Texas Back Institute

VAS Outcome



Texas Back Institute

Discussion

- **Hybrid fusion and TDR adjacent to prior fusion appear to produce good outcomes**
  - **Provided other TDR criteria are met**

Texas Back Institute

Discussion

- Rigorous adherence to selection criteria can help to reduce complications
  - Avoid devices that are too large or too small for patient's anatomy
  - Check bone quality

Texas Back Institute

Discussion

- When in doubt of safety of using TDR, converting to fusion is always an option
  - Particularly in devices are too large, too small, or too tall for the disc space

Texas Back Institute

Discussion

- Cervical TDR outcomes are good
- Should remain good with proper patient selection
  - May improve with refined indications and more disc designs and sizes

Texas Back Institute

TDR at Level Adjacent to Previous Fusion?

- Not included in FDA trials

Texas Back Institute

Spine

BIOMECHANICS

SPINE Volume 40, Number 20, pp 1578-1585

Biomechanical Analysis of Cervical Disc Replacement and Fusion Using Single Level, Two Level, and Hybrid Constructs

Anup A. Gandhi, PhD,*† Swathi Kode, PhD,*† Nicole A. DeVries, PhD,*† Nicole M. Grosland, PhD,*†‡ Joseph D. Smucker, MD,‡ and Douglas C. Fredericks, BS‡

- TDR at level adjacent to an existing fusion is biomechanically favorable to a fusion

Texas Back Institute

Level Adjacent to ACF

- Presented with severe neck pain, bilateral paresthesias and headache
- ACF 4 yrs early, did well afterward

Texas Back Institute


Texas Back Institute